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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,190	11/25/2003	Malka Berndt	06530.0317	4220

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,190	<b>Applicant(s)</b> BERNDT, MALKA	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

This action is in response to applicant's amendment filed on November 7, 2005. Objections to claims 9-10, 20-21, and 28-29 are withdrawn. The Slater 102(b) and 103(a) rejections of claims 1-33 (original) are withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater (U.S. Pat. No. 5,359,993) in view of Malchesky (U.S. Pat. No. 5,518,927).

Slater discloses the device and method according to claims 1, 16, and 24 (all currently amended), except for having the indicator comprise a chemical. Malchesky,

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however, teaches a device to perform a medical procedure comprising a chemical indicator capable of undergoing a color change when exposed to a particular environment for sterilization (col. 1, ln. 7-27 and col. 2, ln. 1-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the indicator of Slater a chemical indicator in view of the teaching of Malchesky as an obvious alternate type of sterilization indicator that is well-known in the art.

Slater discloses the device and method of independent claims 1, 16, and 24 in view of Malchesky, and Slater further discloses the limitations of the dependent claims 2-4, 8-10, 19-21, 27-29, and 33.

Regarding claim 5, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the indicator of Slater, and therefore the indicator of Slater in view of Malchesky, directly on the ring portion as a matter of obvious design choice as stated in the First Office Action.

Regarding claims 6, 13, 17, and 25, the indicator of Malchesky is printed directly on the medical device (col. 6, ln. 43-50).

Regarding claims 7, 18, and 26, the indicator of Malchesky is configured to show a symbol when it undergoes a color change (col. 6, ln. 43-50).

Regarding claims 11 and 30, the indicator of Malchesky is configured to be substantially the same color as a portion of the medical device before being exposed to the particular environment (col. 6, ln. 43-50).

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Regarding claims 12 and 31, the indicator of Malchesky is configured to be a different color than a portion of the medical device after being exposed to the particular environment (col. 6, ln. 43-50).

Regarding claims 14, 22, and 32, the indicator of Malchesky includes a plurality of indicators (col. 6, ln. 30-36).

Regarding claim 15 and 23, each of the plurality of indicators of Malchesky undergoes a color change different from the other of the plurality of indicators (col. 6, ln. 30-36).

Regarding claims 34-36 (all new), the indicator of Malchesky is stationary relative to the device during the color change.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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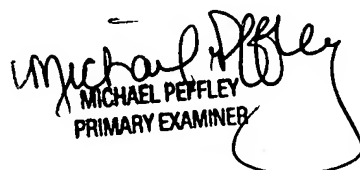
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT/AT  
11/28/05

  
MICHAEL PEFFLEY  
PRIMARY EXAMINER